



Approved for use through 07/31/2006. OMB 0651-0032  
U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

# FEE TRANSMITTAL for FY 2003

Effective 01/01/2003. Patent fees are subject to annual revision.

Applicant claims small entity status. See 37 CFR 1.27

**TOTAL AMOUNT OF PAYMENT** (\$)

180

Complete if Known	
Application Number	10/040,010
Filing Date	January 4, 2002
First Named Inventor	Thomas M. Mills et al.
Examiner Name	Shaojia A. Jiang
Art Unit	1617
Attorney Docket No.	M0351/267875

JUN 01 2004

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## METHOD OF PAYMENT (check all that apply)

Check  Credit card  Money  Other  None Order

Deposit Account:

Deposit Account Number

16-1435

Deposit Account Name

The Director is authorized to: (check all that apply)

- Charge fee(s) indicated below  Credit any overpayments  
 Charge any additional fee(s) during the pendency of this application  
 Charge fee(s) indicated below, except for the filing fee to the above-identified deposit account.

## FEE CALCULATION

### 1. BASIC FILING FEE

Large Entity	Small Entity	Fee Description	Fee Paid
Fee Code (\$)	Fee Code (\$)		
1001 750	2001 375	Utility filing fee	
1002 330	2002 165	Design filing fee	
1003 520	2003 260	Plant filing fee	
1004 750	2004 375	Reissue filing fee	
1005 160	2005 80	Provisional filing fee	
<b>SUBTOTAL (1)</b>			(\$ 0)

### 2. EXTRA CLAIM FEES FOR UTILITY AND REISSUE

Total Claims	Extra Claims	Fee from below	Fee Paid
	-20 ** = 0	X 0 = 0	
Independent Claims	-3 ** = 0	X 0 = 0	
Multiple Dependent		X 0 = 0	

Large Entity	Small Entity	Fee Description
Fee Code (\$)	Fee Code (\$)	
1202 18	2202 9	Claims in excess of 20
1201 84	2201 42	Independent claims in excess of 3
1203 280	2203 140	Multiple dependent claim, if not paid
1204 84	2204 42	** Reissue independent claims over original patent
1205 18	2205 9	** Reissue claims in excess of 20 and over original patent
<b>SUBTOTAL (2)</b>		(\$ 0)

## FEE CALCULATION (continued)

### 3. ADDITIONAL FEES

Large Entity	Small Entity	Fee Description	Fee Paid
Fee Code (\$)	Fee Code (\$)		
1051 130	2051 65	Surcharge - late filing fee or oath	
1052 50	2052 25	Surcharge - late provisional filing fee or cover sheet	
1053 130	1053 130	Non-English specification	
1812 2,520	1812 2,520	For filing a request for reexamination	
1804 920*	1804 920*	Requesting publication of SIR prior to Examiner action	
1805 1,840*	1805 1,840*	Requesting publication of SIR after Examiner action	
1251 110	2251 55	Extension for reply within first month	
1252 410	2252 205	Extension for reply within second month	
1253 930	2253 465	Extension for reply within third month	
1254 1,450	2254 725	Extension for reply within fourth month	
1255 1,970	2255 985	Extension for reply within fifth month	
1401 320	2401 160	Notice of Appeal	
1402 320	2402 160	Filing a brief in support of an appeal	
1403 280	2403 140	Request for oral hearing	
1451 1,510	1451 1,510	Petition to institute a public use proceeding	
1452 110	2452 55	Petition to revive – unavoidable	
1453 1,300	2453 650	Petition to revive – unintentional	
1501 1,300	2501 650	Utility issue fee (or reissue)	
1502 470	2502 235	Design issue fee	
1503 630	2503 315	Plant issue fee	
1460 130	1460 130	Petitions to the Commissioner	
1807 50	1807 50	Processing fee under 37 CFR 1.17 (q)	
1806 180	1806 180	Submission of Information Disclosure Stmt	180
8021 40	8021 40	Recording each patent assignment per property (times number of properties)	
1809 750	2809 375	Filing a submission after final rejection (37 CFR § 1.129(a))	
1810 750	2810 375	For each additional invention to be examined (37 CFR § 1.129(b))	
1801 750	2801 375	Request for Continued Examination (RCE)	
1802 900	1802 900	Request for expedited examination of a design application	
Other fee (specify) _____			

\*Reduced by Basic Filing Fee Paid

**SUBTOTAL (3)**

(\$ 180)

\*\*or number previously paid, if greater; For Reissues, see above

SUBMITTED BY		Complete (if applicable)	
Name (Print/Type)	Cynthia B. Rothschild	Registration No. (Attorney/Agent)	47,040 Telephone (336) 607-7300
Signature		Date	May 14, 2004

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This collection of information is required by 37 CFR 1.17 and 1.27. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing this form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.



## EXPRESS MAIL CERTIFICATE

"Express Mail" Label No. : EV 367 775 805 US

Serial No. : 10/040,010

Applicant(s) : Thomas M. Mills et al.

Filing Date : January 4, 2002

Title : Treatment of Erectile Dysfunction

Examiner : 1617

Group Art Unit : Shaojia A. Jiang

Type of Document(s) : Express Mail Certificate (EV 367 775 805 US);  
Transmittal Form PTO/SB/21;  
Fee Transmittal Form PTO/SB/17;  
Check # 361386 in the amount of \$180;  
Information Disclosure Statement (in duplicate);  
PTO/SB/08a;  
References; and  
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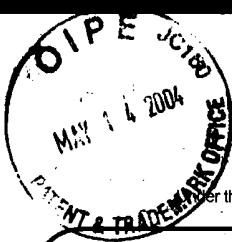
States Postal Service "Express Mail Post Office to Addressee" service under 37 CFR 1.10 on

the date indicated above and are addressed to Mail Stop Amendment, Commissioner for

Patents, P. O. Box 1450, Alexandria, VA 22313-1450.

  
\_\_\_\_\_  
Kay Farmer (signature)

Date Mailed: May 14, 2004



Express Mail EV 367 775 805 US

PTO/SB/21 (08-03)

Approved for use through 07/31/2006. OMB 0651-0031

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

## TRANSMITTAL FORM

(to be used for all correspondence after initial filing)

TRANSMITTAL FORM  (to be used for all correspondence after initial filing)	Application Number	10/040,010	
	Filing Date	January 4, 2002	
	First Named Inventor	Thomas M. Mills et al.	
	Art Unit	1617	
	Examiner Name	Shaojia A. Jiang	
Total Number of Pages in This Submission		Attorney Docket Number	M0351/267875

**ENCLOSURES (check all that apply)**

<input checked="" type="checkbox"/> Fee Transmittal Form  <input checked="" type="checkbox"/> Fee Attached - Check #361386 in the amount of \$180  <input type="checkbox"/> Amendment / Reply  <input type="checkbox"/> After Final  <input type="checkbox"/> Affidavits/declaration(s)  <input type="checkbox"/> Extension of Time Request  <input type="checkbox"/> Express Abandonment Request  <input checked="" type="checkbox"/> Supplemental Information Disclosure Statement  <input type="checkbox"/> Certified Copy of Priority Document(s)  <input type="checkbox"/> Response to Missing Parts/ Incomplete Application  <input type="checkbox"/> Response to Missing Parts under 37 CFR 1.52 or 1.53	<input type="checkbox"/> Drawing(s)  <input type="checkbox"/> Licensing-related Papers  <input type="checkbox"/> Petition  <input type="checkbox"/> Petition to Convert to a Provisional Application  <input type="checkbox"/> Power of Attorney, Revocation Change of Correspondence Address  <input type="checkbox"/> Terminal Disclaimer  <input type="checkbox"/> Request for Refund  <input type="checkbox"/> CD, Number of CD(s) _____	<input type="checkbox"/> After Allowance Communication to Group  <input type="checkbox"/> Appeal Communication to Board of Appeals and Interferences  <input type="checkbox"/> Appeal Communication to Group (Appeal Notice, Brief, Reply Brief)  <input type="checkbox"/> Proprietary Information  <input type="checkbox"/> Status Letter  <input checked="" type="checkbox"/> Other Enclosure(s) (please identify below):
		<b>Express Mail Certificate (EV 367 775 805 US) PTO/SB/08a References Return postcard</b>
Remarks		

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**SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT**

Firm or Individual name	Cynthia B. Rothschild Reg. No. 47040
Signature	
Date	May 14, 2004

**CERTIFICATE OF MAILING**

I hereby certify that this correspondence is being facsimile transmitted to the USPTO or deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on the date shown below.

Typed or printed name	Sent via express mail		
Signature			Date

This collection of information is required by 37 CFR 1.5. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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MAY 14 2002

# FEE TRANSMITTAL for FY 2003

Effective 01/01/2003. Patent fees are subject to annual revision.

 Applicant claims small entity status. See 37 CFR 1.27

TOTAL AMOUNT OF PAYMENT (\$)

180

## Complete if Known

Application Number	10/040,010
Filing Date	January 4, 2002
First Named Inventor	Thomas M. Mills et al.
Examiner Name	Shaojia A. Jiang
Art Unit	1617
Attorney Docket No.	M0351/267875

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## METHOD OF PAYMENT (check all that apply)

 Check    Credit card    Money    Other    None  
 Order
 Deposit Account:

Deposit Account Number	16-1435
Deposit Account Name	

The Director is authorized to: (check all that apply)

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- Charge fee(s) indicated below
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- Charge any additional fee(s) during the pendency of this application
- 
- 
- Charge fee(s) indicated below, except for the filing fee to the above-identified deposit account.

## FEE CALCULATION

## 1. BASIC FILING FEE

Large Entity	Small Entity	Fee Description	Fee Paid
Fee Code	Fee Code (\$)	Fee (\$)	
1001	750	2001	375
1002	330	2002	165
1003	520	2003	260
1004	750	2004	375
1005	160	2005	80

SUBTOTAL (1)

(\$0)

## 2. EXTRA CLAIM FEES FOR UTILITY AND REISSUE

Total Claims	-20 **	=	0	X	Fee from below	Fee Paid
Independent Claims	-3 **	=	0	X		
Multiple Dependent				X		

Large Entity	Small Entity	Fee Description	
Fee Code	Fee Code (\$)	Fee (\$)	
1202	18	2202	9
1201	84	2201	42
1203	280	2203	140
1204	84	2204	42
1205	18	2205	9

SUBTOTAL (2)

(\$0)

## FEE CALCULATION (continued)

## 3. ADDITIONAL FEES

Large Entity	Small Entity	Fee Description	Fee Paid
Fee Code	Fee Code (\$)	Fee (\$)	
1051	130	2051	65
1052	50	2052	25
1053	130	1053	130
1812	2,520	1812	2,520
1804	920*	1804	920*
1805	1,840*	1805	1,840*
1251	110	2251	55
1252	410	2252	205
1253	930	2253	465
1254	1,450	2254	725
1255	1,970	2255	985
1401	320	2401	160
1402	320	2402	160
1403	280	2403	140
1451	1,510	1451	1,510
1452	110	2452	55
1453	1,300	2453	650
1501	1,300	2501	650
1502	470	2502	235
1503	630	2503	315
1460	130	1460	130
1807	50	1807	50
1806	180	1806	180
8021	40	8021	40
1809	750	2809	375
1810	750	2810	375
1801	750	2801	375
1802	900	1802	900

Other fee (specify) \_\_\_\_\_

\*Reduced by Basic Filing Fee Paid

SUBTOTAL (3)

(\$0)

\*\*or number previously paid, if greater; For Reissues, see above

SUBMITTED BY					
Name (Print/Type)	Cynthia B. Rothschild	Registration No. (Attorney/Agent)	47,040	Telephone	Complete (if applicable)
Signature			Date	May 14, 2004	

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EV 367 775 805 US

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of : Thomas M. Mills et al.  
Serial No : 10/040,010  
Filed : January 4, 2002  
For : Treatment of Erectile Dysfunction  
Examiner : Shaojia A. Jiang  
Art Unit : 1617

Commissioner for Patents  
P.O. Box 1450  
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Dear Sir:

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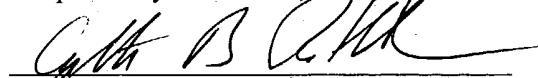
**SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT**

Pursuant to 37 C.F.R. §§ 1.56, 1.97 and 1.98, the attention of the Patent and Trademark Office is hereby directed to the reference listed on the attached Form PTO/SB/08A. A copy of the references listed on the attached form is submitted herewith.

It is respectfully requested that the references listed on the attached form be expressly considered by the Examiner and be made of record in the application and appear among the "References Cited" on any patent to issue therefrom.

This Supplemental Information Disclosure Statement is being submitted after the mailing of a first Office Action in this application. A check in the amount of \$180 is enclosed for the fees due. However, the Commissioner is hereby authorized to charge any additional fees under 37 C.F.R. § 1.16 or § 1.17 which may be required during the entire pendency of this application, or to credit any overpayment, to Deposit Account No. 16-1435. A duplicate of this sheet is attached for that purpose.

Respectfully submitted,

  
\_\_\_\_\_  
Cynthia B. Rothschild  
Reg. No. 47,040

Date: May 14, 2004

KILPATRICK STOCKTON LLP  
1001 West Fourth Street  
Winston-Salem, North Carolina 27101-2400  
(336) 747-7541 (Phone)  
(336) 734-2610 (Facsimile)

18/2004 MBERHE 0000039 10040010

FC:1806

180.00 OP



EV 367 775 805 US

PATENT

THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of : Thomas M. Mills et al.  
Serial No : 10/040,010  
Filed : January 4, 2002  
For : Treatment of Erectile Dysfunction  
Examiner : Shaojia A. Jiang  
Art Unit : 1617

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Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

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Dear Sir:

**SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT**

Pursuant to 37 C.F.R. §§ 1.56, 1.97 and 1.98, the attention of the Patent and Trademark Office is hereby directed to the reference listed on the attached Form PTO/SB/08A. A copy of the references listed on the attached form is submitted herewith.

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Respectfully submitted,

  
Cynthia B. Rothschild  
Reg. No. 47,040

Date: May 14, 2004

KILPATRICK STOCKTON LLP  
1001 West Fourth Street  
Winston-Salem, North Carolina 27101-2400  
(336) 747-7541 (Phone)  
(336) 734-2610 (Facsimile)



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PTO/SB/08a (08-03)

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Approved for use through JUNE 30, 2011

**U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE**

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Subsection for form 1449 <b>SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b> <i>(Use as many sheets as necessary)</i>		<b>Complete if Known</b>	
		<i>Application Number</i>	10/040,010
		<i>Filing Date</i>	January 4, 2002
		<i>First Named Inventor</i>	Thomas M. Mills et al.
		<i>Art Unit</i>	1617
		<i>Examiner Name</i>	Shaojia A. Jiang
<i>Sheet</i>	1	<i>of</i>	2
		<i>Attorney Docket Number</i>	M0351/267875

## **U.S. PATENT DOCUMENTS**

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## **FOREIGN PATENT DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
		Country Code <sup>3</sup> - Number <sup>4</sup> - Kind Code <sup>5</sup> ( <i>if known</i> )				

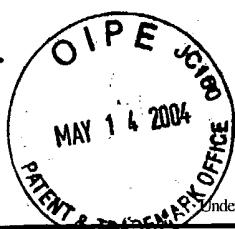
#### NON-PATENT LITERATURE DOCUMENTS

Examiner Initials *	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.
	1	MILLS, T. M., et al., "Nitric oxide inhibits RhoA/Rho-kinase signaling to cause penile erection, " <i>Eur J Pharmacol</i> 439: 173-174, 2002
	2	MILLS, T. M., et al., "Inhibition of Tonic Contraction - a Novel Way to Approach Erectile Dysfunction?" <i>J Androl</i> , 23, S5-S9, 2002
	3	MILLS, T. M., et al., "The role of Androgens in the Erectile Response: a 1999 Perspective, " <i>Mol Urol</i> , 3, 75-86, 1999

Examiner Signature		Date Considered	
-----------------------	--	--------------------	--

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.<sup>1</sup> Applicant's unique citation designation number (optional).<sup>2</sup> See Kinds Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04.<sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3).<sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document.<sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible.<sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.



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PTO/SB/08b(08-03)

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U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

Substitute for form 1449B/PTO

## SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 2 of 2

*Complete if Known*

<i>Application Number</i>	10/040,010
<i>Filing Date</i>	January 4, 2002
<i>First Named Inventor</i>	Thomas M. Mills et al.
<i>Art Unit</i>	1617
<i>Examiner Name</i>	Shaojia A. Jiang
<i>Attorney Docket Number</i>	M0351/267875

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## NON PATENT LITERATURE DOCUMENTS

Examiner Initials *	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
	4	MILLS, T. M., et al., "Endothelin-1-induced Vasoconstriction is Inhibited During Erection in Rats," <i>Am J Physiol Regul Integr Comp Physiol</i> 281, R476-R483, 2001	
	5	MILLS, T.M., et al., "Androgens and Penile Erection: A Review," <i>J Androl</i> 17, 633-638, 1996	
	6	MILLS, T. M., et al., "Sites of Androgenic Regulation of Cavernosal Blood Pressure During Penile Erection in the Rat," <i>Int J Impot Res</i> 8, 29-34, 1996	
	7	MILLS, T. M., et al., "Erection Modulates the Endothelin-1 Effect on the Rat Penis" (Abstract) <i>Int J Impot Res</i> 12, Suppl 2, S22, 2000	
	8	SAKURADA, S., et al., "Rho Activation in Excitatory Agonist-stimulated Vascular Smooth Muscle" (Abstract), <i>Am J. Physiol Cell Physiol</i> 281, C571-C578, 2001	
	9	SOMLYO, A. P., et al., "Signal Transduction and Regulation in Smooth Muscle," <i>Nature</i> 372, 231-236, 1994	
	10	UEHATA, M., et al., "Calcium Sensitization of Smooth Muscle Mediated by a Rho-associated Protein Kinase in Hypertension," <i>Nature</i> , 389, 990-994, 1997	
	11	WANG, H., et al., "RhoA-mediated Ca <sub>2+</sub> Sensitization in Erectile Function," <i>J. Biol. Chem</i> , 277, 30614-30621, 2002	
	12	WINGARD, C. J., et al., "Improved Erectile Function After Rho-kinase Inhibition in a Rat Castrate Model of Erectile Dysfunction," <i>Am J Physiol Regul Integr Comp Physiol</i> , 284, R1572-R1579, 2003	
	13	WINGARD, C. J., et al., "RhoA-RHO kinase Mediates Synergistic ET-1 and Phenylephrine Contraction of Rat Corpus Cavernosum," <i>Am J Physiol Regul Integr Comp Physiol</i> , 285 R1145-R1152, 2003 First published July 31, 2003; 10.1152/ajpregu.00329.2003	
	14	DAI, Y., et al. "Topical Application of a Rho-kinase Inhibitor in Rats Causes Penile Erection," <i>Int J Impot Res.</i> , Feb. 12, 2004, PMID: 14961052	

Examiner Signature		Date Considered	
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\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup>Applicant's unique citation designation number (optional). <sup>2</sup>Applicant is to place a check mark here if English language Translation is attached.

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